K082857

510(k) SUMMARY— Renegade Wheelchair

JAN - 6 2009

Submitter Name:	Alpha One
Submitter Address:	127 Main Street Portland, Maine 04106
Contact Person:	Brad Strause
Phone Number:	207-767-2189
Fax Number:	207-799-8346
Date Prepared:	September 24, 2008
Device Trade Name:	Renegade Wheelchair
Device Common Name:	Mechanical special grade wheelchair
Classification Numbers:	21 CFR 890.3850 and 21 CFR 890.3880
Classification Names:	Wheelchair, Mechanical and Wheelchair, Special Grade
Product Codes:	IOR and IQC
Predicate Devices:	Stryker Sorano Wheelchair (K051369) Poirier S.A. Arnas Wheelchair (K840631)
Statement of Intended Use:	The Renegade Wheelchair is a versatile, mechanical wheelchair intended for indoor and outdoor use.
Device Description:	The Renegade is designed to offer the user the option of conventional hand-to-wheel propulsion, or the use of push-bar levers which provide thrust by way of a gear and chain system. Each wheel has multiple gears and independent brakes, providing versatility and control. The wheelchair is fitted with accessory holders to provide a means to carry sports and recreational equipment.
Comparison to the Predicate Devices:	This device, with respect to material composition, technical characteristics, and intended use, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN – 6 2009

Alpha One
% Trisler Consulting, LLC
Ms. Pasty J. Trisler
5600 Wisconsin Ave, Suite 509
Chevy Chase, Maryland 20815

Re: K082857
Trade Name: Renegade Wheelchair
Regulation Number: 21 CFR 890.3880
Regulation Names: Special grade wheelchair
Regulatory Class: II
Product Code: IQC
Dated: December 10, 2008
Received: December 12, 2008

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Renegade Wheelchair

Indications for Use:

The Renegade Wheelchair is a versatile, mechanical wheelchair intended for indoor and outdoor use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___x___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082857